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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,069	01/03/2007	Sudeepta Aggarwal	GNE-0269 R1	5360

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Goodwin Procter LLP
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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,069	AGGARWAL ET AL.	
	Examiner	Art Unit	
	NIRMAL S. BASI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/26/08, 9/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed 1/12/09 has been entered.

2.. Applicant's election with traverse of Group X (Claims 41-43) and the addition of new claims 44-52 on 1/21/09, is acknowledged. Claims 41-52 are examined below. Applicant provided no reasons for the traversal.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. A substitute specification is required pursuant to 37 CFR 1.125(a) because many of the pages have missing text, e.g. pages 137, 143, 149, 167, 173, 179, 191, 197, 203 etc.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because many of the drawing have missing parts, e.g. Figures 1, 6, 12, 18, 24, 201, 212, 216 etc. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

5. The description of the drawings in the specification is objected to because each Figure must labeled and described separately in the Brief Description of the Drawings. For example: Figure 1 should be labeled as Figures 3A-C and then each panel described separately, or the equivalent, as required by 37 C.F.R. 1.84 (u)(1). This application contains 2442 Figures and they must all comply as required by 37 C.F.R. 1.84 (u)(1).

Appropriate correction is required for all figures with more than one panel

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 41-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 is indefinite because it is not clear what is an immune related disease so as to allow the metes and bounds of the claim to be determined. Those diseases that would be considered as immune related are not defined in the specification so as to allow the metes and bounds of the claim to be determined.

Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are the method of detecting the level of expression of a gene encoding PRO polypeptide. The method discloses no steps on how the expression of the gene is detected.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are the method of detecting the formation of a complex between the antibody and the polypeptide. The method discloses no steps on how the formation of a complex between the antibody and the polypeptide is detected.

Claim 43 is indefinite because it is not clear what is an inflammatory immune response so as to allow the metes and bounds of the claim to be determined. Those responses that would be considered as inflammatory immune responses are not defined in the specification so as to allow the metes and bounds of the claim to be determined.

Claim 44 recites the limitation "PRO85142" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 44 is indefinite because it is not clear what probes would be considered specific for the nucleic acid encoding PRO85142 since no specific probes for the nucleic acid encoding PRO85142 are disclosed.

Claim 45 is indefinite because stringent conditions of hybridization are not specified. It is not clear what the "stringent conditions" are. The metes and bounds of the group of sequences that would meet the limitations of the claim depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which nucleic acid sequences remain specifically bound to the claimed polynucleotide the metes and bounds of the claim cannot be determined without the disclosure of said conditions.

Claim 46 is rejected because it is not clear what is being claimed. The claim contains more than12 misplaced periods. It is suggested the claim be checked for grammatical errors rewritten with the periods.

Claims 47-52 are rejected for depending on a rejected base claim.

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 41-52 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

A specific utility is a utility that is specific to the subject matter claimed, as opposed to a general utility that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specifications disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A well established utility must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention. Applicant has asserted utilities for the specifically claimed invention of claims 41-52. The specification discloses a nucleic acid molecule (SEQ ID NO:2387) encoding the polypeptide PRO85142 (SEQ ID NO:2388). The nucleic acid is contained in a clone designated as clone DNA329612. The contemplated uses of PRO85142 are screening methods for PRO85142, assays for PRO85143 activity, and treatment of conditions related to aberrant PRO85143 activity and disease diagnosis of PRO85142 related diseases. The utilities disclosed in the specification are based on methods of using claimed PRO85143 as a target for diagnosis and treatment of disorders, for drug-screening methods and to identify agonists and antagonists for diagnosis and treatment.

The specification only discloses the sequence of PRO85142 nucleic acid and its encoded protein. There is no disclosure of PRO85142 functional activity or pattern of expression in various tissues. There is no disclosure of proteins related to PRO85142 by either functional or sequence identity. The activity of PRO85142 polypeptide and it's physical function are unknown. In instant case using PRO85143 as a diagnostic for immune related disorders leaves a lot to the imagination as to its role in said disorders. Not a single disorder is disclosed which is implicated in PRO85143 function or dysfunction. Therefore, it is not known what diseases are involved in PRO85143 function or dysfunction. In essence, further experimentation is required to determine a utility for PRO85143.

Pertaining to claimed invention there is no disclosure of the ligands that activate or inhibit PRO85143 activity, receptors that activate or inhibit PRO85143 activity or the PRO85143 regulated cellular functions. The specification discloses hundreds of PRO polypeptides but does not disclose any specific activity associated with the claimed PRO85143 of instant invention. The specification suggests that PRO85143 may be associated with immune related disease. The question is what disease and what is its role in the disease state. In light of the specification the skilled artisan can speculate that PRO85143 of instant invention is a protein, which may belong to the diverse family of immune related proteins. PRO85143 may play a role in cellular signaling, but it is not known what role PRO85143 plays what would be the use of detecting PRO85143 function, apart from determining PRO85143 dysfunction and as targets for drug discovery

The utilities asserted by Applicant are not specific or substantial. Since no specific function of PRO85143of instant invention is looking for PRO85143 dysfunction, assaying its presence or assaying for its ligands is not considered a well established utility, the hypothesized functions are based entirely on conjecture. The asserted utilities are not specific to instant polypeptide, but rather are based on family attributes. Neither the specification nor the art of record disclose the nucleic acid of SEQ ID NO:2386 encoding the protein of SEQ ID NO:2388 or fragments thereof useful to identify drugs that affect said protein and modulate its activity. Similarly, neither the specification nor the art of record disclose any instances where disorders can be affected by interfering with the activity of PRO85143. Thus the corresponding asserted utilities are essentially methods of using PRO85143 polypeptide and nucleic acids to identify or treat disease states associated with PRO85143 dysfunction and as targets for drug discovery. Therefore the asserted utilities are essentially methods of testing for or for potentially treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating or testing for compounds that interact with PRO85143 polypeptide or nucleic acid, which may be implicated in an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. Since neither the specification nor the art of record disclose any activities or properties that would constitute a real world context of use for the PRO85143, further experimentation is necessary to attribute a utility to the claimed nucleic acids and fragments thereof. See Brenner v. Manson, 383

U.S. 519, 535B36, 148 USPQ 689, 696 (1966) (noting that Congress intended that no patent be granted on a chemical compound whose sole utility consists of its potential role as an object of use-testing, and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Therefore for the reason given above PRO85143 lacks utility.

8. Claims 41-52 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Since neither the specification nor the art of record disclose any activities or properties that would constitute a real world context of use for the PRO85143 polypeptide, further experimentation is necessary to attribute a utility to the method of using the PRO85143.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIRMAL S. BASI whose telephone number is (571)272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nirmal S. Basi/
Examiner, Art Unit 1646

/Michael Pak/
Primary Examiner, Art Unit 1646